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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/785,221

02/24/2004

Avi Ashkenazi

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02/22/2007

GENENTECH, INC.

1 DNA WAY

SOUTH SAN FRANCISCO, CA 94080

EXAMINER

HADDAD, MAHER M

ART UNIT

PAPER NUMBER

1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/785,221	Applicant(s) ASHKENAZI ET AL.	
	Examiner Maher M. Haddad	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 54-58 is/are allowed.
- 6) ☒ Claim(s) 49-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 12/4/06, is acknowledged.
2. Claims 49-58 are pending and under examination in the instant application.
3. Applicant request that 9/17/98 date (PCT/US98/19437) be accorded as the earliest priority to claims 49-63. However, while the PCT/US98/19437 discloses the amino acid sequence and the DNA sequence of claimed PRO245 without enabling use. The earliest date that provides an enabling use of PRO245 is PCT/US98/24855) filed 11/20/1998.
4. The following new ground of rejection is necessitated by the amendment submitted 12/4/06.
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 49-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The phrase "having at least 95% sequence identity" claimed in claim 49, line 1, represents a departure from the specification and the claims as originally filed.

Applicant's amendment filed 12/4/06 points to the specification on page 12, lines 24-33 for support for the newly added limitations "having at least 95% sequence identity" as claimed in claim 49. However, the specification does not provide a clear support of this limitation. The instant claims now recite limitations, which were not clearly disclosed in the specification and recited in the claims as originally filed.

Applicant's arguments, filed 12/4/06, have been fully considered, but have not been found convincing.

Applicant argues that the page 12, lines 24-33 section is intended to provide a definition for PRO301 and PRO245 variants, but, due to a typographical error, the rest of the paragraph refers only to PRO301 variants. Applicant contends that one of ordinary skill in the art would immediately recognize that the paragraph at page 12, lines 24-33 contains a typographical error, and would also know how to correct that error, by extending the disclosure to PRO245 variants. Accordingly, the cited paragraph provides clear support for PRO245 variants having at least about 95% sequence identity to the sequence of PRO245.

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However, obviousness is not the standard for the addition of new limitations to the disclosure as filed. It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). New Matter is a written description issue.

7. Claims 49-53 are rejected under 35 U.S.C 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid having (a) the nucleotide sequence encoding the polypeptide of SEQ ID NO:9, (b) the nucleic acid sequence of SEQ ID NO: 8, (c) the full-length coding sequence of SEQ ID NO: 8 or the cDNA deposited under ATCC accession number 209265, a vector comprising the nucleic acid molecule, a host cell comprising the vector and a process for producing the PRO245 polypeptide of SEQ ID NO: 9, wherein PRO245 has the ability to inhibit of VEGF stimulated proliferation of endothelial cells, does not reasonably provide enablement for any isolated nucleic acid molecule comprising having at least 95% sequence identity to the polypeptide of SEQ ID NO:9 wherein said polypeptide is capable inhibiting VEGF-stimulated endothelial cell growth . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant argues that methods of making variants of native polypeptides were well known in the art at the effective filing date of the present application. Further, the specification provides detailed description of an assay for testing the inhibition of VEGF-stimulated endothelial cell. Applicant concludes that one of ordinary skill in the art at the time the present invention was made would have been able to make and test the claimed variants of the polypeptide of claimed SEQ ID NO: 9.

However, there does not appear to be sufficient guidance in the specification as filed as to how the skilled artisan would make and use the various nucleic acids recited in the instant claims. A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. There is insufficient guidance to direct a person of skill in the art to select particular sequences or sequence lengths as essential for inhibiting VEGF-stimulated endothelial cell growth. Without detailed direction as to which nucleic acid sequences are essential to the function of the encoded polypeptide, a person of skill in the art would not be able to determine without undue experimentation which of the plethora of nucleic acid sequences encompassed by the instant claims would share the ability to inhibit VEGF-stimulated endothelial cell growth of the encoded polypeptide of SEQ ID NO:9, other than the nucleic acid of SEQ ID NO:8 encoding SEQ ID NO:9

8. Claims 54-58 are allowable.

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 19, 2007



Maher Haddad, Ph.D.
Primary Examiner
Technology Center 1600